

Jacksonville State University

Institutional Review Board

2004 Annual Report

I. General Information

a. Name. The name of this committee is Jacksonville State University Institutional Review Board (IRB).

b. Purpose and Scope. The Institutional Review Board (IRB) is a committee that reviews all JSU research involving human participants and is responsible to the President. The purpose of the IRB is to assure that research is conducted in an ethical manner, specifically in accordance with Department of Health and Human Services regulations (45 CFR 46 Protection of Human Subjects). This includes ensuring that risks to participants are minimized, the selection of participants, is equitable and participants are informed fully of what their participation will entail.

The policy on the use of human subjects in research applies to any activity deemed to be research at Jacksonville State University. The applicability of this policy is to all entities of the university: faculty, administration, staff, students and contracted consultants. This policy applies to any research activity using human subjects that is directly or indirectly supported by the university.

The full text of JSU's "Policy on Use of Human Subjects in Research" is available on the Academic Affairs web site at <http://www.jsu.edu/depart/avpasa/humansubjects.html> and is reviewed and updated annually.

c. Membership. For 2003-2004, the committee consisted of the following membership:

Dr. Joe Delap, Secretary (Ex Officio)
Dr. Joann Williams, Chair
Dr. Jennifer Gross
Dr. Bob Hymer
Dr. Martha Merrill
Dr. Kay Williams
Dr. Laura Weinkauff

d. Records. Committee Records are maintained by the Secretary and housed in the Office of the Associate Vice President for Academic Affairs, 201 Bibb Graves Hall.

II. Activities and Significant Accomplishments

a. Applications. The IRB reviewed 23 research proposals during the academic year 2003-2004 (as of date of report submission). Of these, 20 were exempt, 2 were expedited and one was fully reviewed. Minutes of fully reviewed applications are included in III.a. The names of all applicants and projects are attached in III.b. All applications were eventually approved.

b. FWA. Prior to 2003-2004, JSU's Institutional Review Board was registered with the federal government, but it did not have a Federal-Wide Assurance (FWA). In November of 2003, with the generous support of the President's Office and others, JSU applied for and was awarded the FWA. According to the Office of Human Research Protections, "[t]he Federal Policy (Common Rule) for the protection of human subjects requires that each institution 'engaged' in Federally-supported human subject research file an 'Assurance' of protection for human subjects. The Assurance formalizes the institution's commitment to protect human subjects. The requirement to file an Assurance includes both 'awardee' and collaborating 'performance site' institutions." JSU's successful application attests to its continued commitment to ensure the protection of human research subjects and places the university among a select number of institutions that have acquired this distinction.

III. Appendix

a. Minutes of IRB Meetings 2003-2004

Institutional Review Board (IRB) meeting of January 9, 2004

Meeting was conducted by electronic mail.

Members responding: Joe Delap (ex-officio), Sherron DeWeese, Jennifer Gross, Robert Hymer, Martha Merrill, Laura Weinkauff, Joann Williams and Kay Williams.

Members not responding: None.

After some discussion, the responding membership approved unanimously, via email response, an application from Drs. Jane Cash, Howard Frumkin and Martha Lavender for research to be conducted by the Anniston Environmental Health Consortium on the Anniston Health Registry.

Discussion of the application:

Dr. Martha Merrill's comment:

"I do not have any issues about the proposal you sent to the committee members. The study will be fully explained to the participants, the parents are responsible for registering minor children, and the privacy issues are adequately addressed."

Dr. Joann Williams had two concerns regarding this proposal. Her concerns and Dr. Lavender's responses are repeated here verbatim:

Dr. Williams' first concern:

"The first concern is always present when minor subjects are involved. In the attachment of Research Subject Authorization, the parents or guardians of minor participants are signing that the minor has volunteered to be included. I don't think that there is anyway that we can verify that they have volunteered. Additionally, since this is only a registry it is probable a minor concerned. The later studies would be responsible to determine whether or not the minor is a volunteer. I just want to call this to the attention of the committee."

Dr. Lavender's (PI's) response:

"Assent is addressed for children 12-17 years of age. Parents or legal guardians are expected to sign for children under 18 years. I agree that there is no way for our IRB to verify that the children have volunteered (just as in health care services/delivery). That decision rests with the parents until the child is of age (or according to IRB rules that the child is of age to give assent)."

Dr. Williams' second concern:

"The second concern is more crucial and I would like answered before final approval. How will the consortium contact the minor children when they reach legal adulthood to continue in the registry or to be removed from this registry? At that point and time, these individuals should have the right to withdraw from the registry and may not be aware of this right. I realize that there are a lot of problems associated with contacting these individuals but a method to contact in the future should be established at this time. An addendum to this proposal describing the procedure would be sufficient."

Dr. Lavender's (PI's) response:

"This registry (and any data collected as part of the Consortium) is designed for the purposes of this funded 3-year study. Its longevity is the life of the grant. I haven't any idea that the registry would be accessed after our study unless another study is funded and approved through IRB for a longitudinal study. At that time, this important issue would have to be addressed."

Dr. Williams' final comment:

"Thank you for the response to my questions. Based on these responses and the original application, I can then assume that any child who is of assent and turns 18 during the course of the grant will be able to remove [him]self from the registry. Since these procedures are in place, I do not see any other problems with application. I vote that this application be approved at this time."

FACULTY NAME	DEPT.	TITLE OF PROJECT	NEW	RENEW	DATE REC'D.	ACTION REQUESTED	APPROVED
James L. Thomas	Mgt, Mkt, & Info Mgmt	Calhoun County: Looking Ahead	X		1/8/4	Exempt	Exempt 01/08/04
Cash, Jane & Lavender, Martha	Nursing	Anniston Health Registry	X		1/6/4	Full Board Review	Full Board Review 1/6/04
Thomas, James	Mgmt, Mkt	Satisfaction with Monopolistic Services & Clients' Commitment to the Organization	X		1/29/4	Exempt	Exempt 01/29/04
LoConto, David	Soc. & Soc. Work	Groups in Society: An Analysis of Labeling	X		1/30/4	Exempt	Exempt 1/30/04
Smith, Tim	Instit. Effec.	JSU Faculty Perception of Academic Dishonesty	X		2/6/4	Exempt	Exempt 2/6/04
Latham, Sarah	Nursing & Health Sc.	Student Survey Related to Administrative Processes at JSU	X		2/11/4	Exempt	Exempt 2/11/04
Bryson, Jeff	Psychology	Dreaming and Identity	X		2/25/4	Exempt	Exempt 2/25/04
Charnigo, Laurie	Library	Survey of Wireless Networks in Small-Medium Sized Libraries	X		2/26/5	Exempt	Exempt 2/27/04
Aveni, Adrian	Sociology & Social Work	Evaluation of Ethnocentrism Scales	X		3/4/4	Exempt	Exempt 3/5/04
Thomas, James	Mgmt., Mkt, & Info Mgmt	Assessing the Learning of Marketing Ethics: The Role of Perceived Moral Intensity	X		3/29/4	Exempt	Exempt 3/29/04
Simpson, Cathy	PSY	Program Evaluation and Community Outreach Services for HIV and Substance Abuse Prevention		X	04/16/04	Expedited Review	Expedited Review 4/16/04

FACULTY NAME	DEPT.	TITLE OF PROJECT	NEW	RENEW	DATE REC'D.	ACTION REQUESTED	APPROVED
King, Nina	C&I	The Development of Professionalism in Early Childhood Education Pre-service Teachers	X		4/21/4	Exempt	Exempt 4/21/04
Smith, Tim	Institutional Effectiveness	Institutional Research Function	X		4/21/4	Exempt	Exempt 4/21/04
Jones, Cynthia	Educ. Res.	Factors that attribute to teacher stress in secondary education	X		5/17/4	Exempt	Exempt 5/17/04
Thomas, James	Mgt/ Mkt	Shopping as a Coping Strategy: Mediating Effect on Materialism	X		6/2/4	Exempt	Exempt 6/2/04

Submitted 1 July 2004 by Joe Delap, Executive Secretary, JSU IRB